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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Licensing Committee Report

Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
John Tilley, R.Ph.
Richard Benson, Public Board Member

Report of December 1, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy approve the proposed legislation to define compounding, anticipatory compounding and contractual arrangements for compounding and proposed regulations to establish the requirements for general compounding.

Discussion
The Board of Pharmacy initially formed the Workgroup on Compounding in part to respond to a request from the Department of Health Services – Food and Drug Branch to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer. The goal was to work with the compounding profession to respond to this request as well as identify and address "gaps" in pharmacy law related to pharmacy compounding. At each workgroup meeting, there have been over 30 participants who have provided valuable input into the process.

Dr. Schell, who chaired the workgroup, explained that at the September meeting a concept draft to regulate general compounding by pharmacies was presented and discussed. Based on the discussion and the comments that were provided, proposed statutory and regulatory amendments were drafted for the workgroup's review. The Workgroup on Compounding met on December 1st (prior to the Licensing Committee meeting) for final review and discussion of the proposal. It was noted that the workgroup members would have the opportunity to address any concerns regarding the proposal to this committee and ultimately to the board.

Dr. Schell explained that the proposal that is being recommended for the Licensing Committee's consideration includes a definition of compounding, which currently is not defined in pharmacy law. It requires that the pharmacist have a professional relationship with both the prescriber and the patient. The proposal also addresses the issues of central fill (where a pharmacy may

contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug product, and requirements for facilities and equipment. The proposal also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications.

Dr. Schell reiterated that at the September workgroup meeting, there was considerable discussion regarding the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s). As stated previously, one of the initial requests from DHS was for the board to identify the criteria it uses to determine when a compounding pharmacy would be considered a manufacturer. While one of the workgroup subcommittees updated the list of factors that the board developed many years ago, board counsel explained that the proposed "factors" for distinguishing compounding from manufacturing would at best be considered "guidelines," and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

Further, counsel advised that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer.

While compounding is included in the definition of manufacturing, a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner).

Therefore, Dr. Schell concluded that based on counsel's advice the Board of Pharmacy's priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. This proposal provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety. **(Attachment A)**

On January 7, 2005, the board received comments from FDA regarding the draft general compounding proposal that was provided last September. FDA stated that it is their position that it generally doesn't sanction compounding drugs for third parties to resell to individual patients. Consistent with this position, it is FDA's belief that pharmacies normally should compound their own products. FDA likely would not exercise enforcement discretion towards a pharmacy that compounds drugs to be re-sold by other pharmacies, unless there is a specific need for this arrangement. In such cases, FDA stated that it would expect the compounding pharmacy to document patient-specific need for the compounded product. **(Attachment B)**

RECOMMENDATION 2 (Not a Committee Recommendation)

That the Board of Pharmacy consider the approval of the School of Pharmacy at the Palm Beach Atlantic University.

Discussion
The board received an intern pharmacist application from a student at the School of Pharmacy at the Palm Beach Atlantic University. This application was received after the notice of the Licensing Committee agenda and therefore, could not be considered by the committee. ACPE has granted the school candidate status in 2002 and reaffirmed this status last year.

Precandidate status is the lowest of the ACPE provisional accreditations, and students who graduate from such a school would not be eligible for pharmacist licensure. The ACPE states that precandidate schools have the concepts of an acceptable ACPE program committed to paper, but the program components have not yet been fully implemented.

"Candidate Status" is the next provisional level of ACPE accreditation, which would allow graduates from such a school to become licensed pharmacists. In order to be fully ACPE accredited, the school must have graduated one class of students, among other conditions.

Internship is an integral part of the pharmacy education of students. This obviously creates a problem for students in such new programs where state licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework as a condition of issuing an intern license.

The board has a pending regulation change which it will take action on at this meeting. The change is to amend section 1719 that defines "recognized schools of pharmacy" as a school of pharmacy accredited, or granted candidate status, by the Accreditation Counsel for Pharmacy Education or otherwise recognized by the board. Recognition of the School of Pharmacy at the Palm Beach Atlantic University is consistent with the pending regulation change.

NO ACTION

Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients

The Licensing Committee was provided with a background document that gave an overview on the many issues and questions that the Board of Pharmacy has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin discussion on how the board should address these many issues that don't fit the traditional statutory definition of pharmacy practice and the independent practice of pharmacists as health care providers. The committee agreed to address these issues through its committee meetings in 2005. **(Attachment C)**

Implementation of AB 2628 (Chapter 887, Statutes of 2004) Regarding the Licensure of Wholesalers and Nonresident Wholesalers

Governor Schwarzenegger signed Assembly Bill 2682, on September 29, 2004. This bill makes changes to several Business and Professions Code sections specific to the licensing requirements for wholesalers located outside of California who ship, mail or delivers dangerous drugs or devices into California. Because of the significant changes, the requirements will be phased in over the next two years. The following is a brief description of these changes.

- B & P 4043 – Changes that the name of a wholesaler shipping drugs into California from an out-of-state distributor to a nonresident wholesaler. This change is effective January 1, 2006.
- B & P 4161 – Requires any out-of-state distributor who ships, mails, or delivers dangerous drugs or devices into California to be licensed with the board. Previously any business that that shipped into California to another California licensed wholesaler was exempt from obtaining a California license. This changed is effective January 1, 2005. Effective January 1, 2006, B & P 4161 is again amended to change the name from out-of-state distributor to nonresident wholesaler and to change the title of "exemptee-in-charge" to "designated representative-in-charge."
- B & P 4162.5 – Requires an applicant for licensure or renewal to submit a surety bond of $100,000 for each nonresident wholesaler site licensed or to be licensed. The board may accept a surety of bond of $25,000 if the annual gross receipts of the previous tax year, as a nonresident wholesale is $10,000,000 or less. This section takes effect January 1, 2006.

To facilitate the implementation of these changes, board staff, along with DAG Joshua Room, has reviewed and revised the application forms, requirements and processes for both the wholesaler and nonresident wholesalers. It is anticipated that the new forms will be available on the board's website by mid-December.

Competency Committee Report
The Board of Pharmacy transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. As of December 31, 2004, the board had received over 2,600 applications to take the California license examinations, and since June 2004, 1,299 applicants have been licensed as pharmacists. The most recent pass rate for the CPJE is 85%. **(Attachment D)**

Workgroup on Compounding Meeting Summary of December 1, 2004
(Attachment E)

Meeting Summary of December 1, 2004
(Attachment F)

Quarterly Status Report on Committee Strategic Objectives for 2004/05
(Attachment G)

Report to the California Legislature on the Effect of Requiring Remedial Education for Candidates who Fail the Pharmacist Licensure Examination Four Times

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times, are required to take 16 units of education in pharmacy in a school approved by ACPE or by the board before they can retake the examinations. This provision will be repealed January 1, 2005, unless the sunset date for this provision is extended.

The board sponsored the provision to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact, there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The provision itself was modeled after a similar provision enacted for the dental examination.

When the provision was enacted in 1997, the board was also mandated to provide a report to the Legislature after June 1, 2004 and before December 31, 2004 on the effect of this provision in four areas. These areas are:

1. The number of applicants taking the examination and the number who fail the examination for the fourth time
2. The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education program.
3. The number of applicants who, after filing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.
4. To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

Since the examination structure itself was greatly altered this year, the board sponsored legislation that extended the sunset date for the provision to allow more time to evaluate the effect of the provision on the new examination structure. **(Attachment H)**

ATTACHMENT A

Section 4019.5 of the Business and Professions Code is added to read:

(a) "Compounding" means any the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form, flavor or delivery system of a drug.
(2) Altering the strength of a drug.
(3) Combining components or active ingredients.
(4) Preparing a drug product from bulk chemicals.

(b) "Compounding" shall not include the reconstitution of a drug pursuant to the manufacturers' direction for oral, rectal or topical administration.

Section 4033 of the Business and Professions Code is repealed:

4033. ~~(a) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.~~
~~(b) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~
~~(c) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.~~ [1]

Section 4037 of the Business and Professions Code is amended to read:

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where dangerous drugs and dangerous devices are stored. ~~prescriptions are compounded.~~ "Pharmacy" includes, but is not limited to, any area, place, or premises ~~described in a~~ licensed ~~issued~~ by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, ~~manufactured,~~ derived, compounded, or repackaged, ~~and from which the controlled substances, dangerous drugs,~~ or ~~dangerous devices are~~ furnished, sold, or dispensed at retail.
(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

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[1] Subdivisions (b) and (c) of current Business and Professions Code section 4033 have been relocated to new Business and Professions Code section 4123. Subdivision (a) of current section 4033 is inconsistent with federal and state laws defining compounding as a subset of manufacturing, rather than as an exception thereto. For instance, California Health and Safety Code section 109970 defines "manufacture" as "preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic," including "repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic," although not "repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer." (See also 21 U.S.C. § 360).

Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture,~~ compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.
(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

Section 4123 of the Business and Professions Code is amended to read:

4123. Compounding Drug Products

~~Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.~~

(a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.
(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.
(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for such drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.
(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.
(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.
(f) Notwithstanding any other provision of this chapter, a pharmacist may:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to receipt of the prescription.
(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

~~**§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.**~~

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~

~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~

~~(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and~~

~~(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.~~

~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~

~~(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.~~

~~**§1716.2. Record Requirements--Compounding for Future Furnishing.**~~

~~(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:~~

~~(1) The date of preparation.~~

~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

~~(7) The quantity in units of finished products or grams of raw materials.~~

~~(8) The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

Article 4.5 General Compounding

§1735. Definitions

(a) "Integrity" means the drug product will retain its potency until the beyond use date noted on the label.

(b) "Quality" means the drug product is free of contaminants and contains those active ingredients indicated on the label.

(c) "Strength" means the amount of active ingredient in each unit of the drug product.

(d) As used in Business and Professions Code Section 4052(a)(1),

(1) "Reasonable quantity" means that quantity of a drug product which:
(A) is sufficient for that prescriber's office use; and
(B) is reasonable considering the intended use of the compounded drug product and nature of the prescriber's practice; and
(C) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for strength, quality and integrity of the drug product.

(2) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.[1]

(e) As used in Business and Professions Code section 4123(c), a "limited quantity" of a drug product compounded prior to receipt of individual prescriptions means no more than a three (3) month supply of a compounded drug product, except that for compounded drug products intended solely for external use "limited quantity" means no more than a one (1) year supply.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, and 4052, Business and Professions Code.

§1735.1. Requirements

(a) Excluding sterile to sterile admixtures, a drug product may not be compounded without a master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Inactive ingredients to be used.
(3) Process and/or procedure used to prepare the drug product.
(4) Quality reviews required at each step in preparation of the drug product.
(5) Post-compounding process or procedures required, if any.
(6) Beyond use dating requirements.

(b) Pharmacists who compound drug products, or supervise the compounding of drug products, shall be responsible for:

(1) Assuring that the drug product retains its strength, quality, and integrity until dispensed to a patient or furnished to a prescriber for office use.
(2) Assuring that the drug product has been prepared, labeled, stored and delivered according to compendial and other applicable requirements.
(3) Assuring that all the components are used and stored in the pharmacy according to compendial and other applicable requirements to maintain their strength, quality and integrity.

(c) The beyond use date of the drug product shall not exceed 180 days or the shortest expiration date of any component in the drug product unless a longer date is supported by stability studies. Shorter dating than set forth in this subsection shall be used when deemed appropriate in the professional judgment of the pharmacist.

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[1] Moved from 1716.1

(d) A pharmacy that contracts with another pharmacy pursuant to Business and Professions Code section 4123 shall label the drug product container with all the information required by Business and Professions Code section 4076 and the name and address of the pharmacy that compounded the drug product.
(e) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. The self-assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4052, and 4076, Business and Professions Code.

§1735.2. Records

(a) Excluding sterile to sterile admixtures, for each drug product, a compounding record shall be made that includes at least:

(1) The information required of a master formula record.
(2) The date the drug product was compounded.
(3) The identities of the pharmacy personnel and their roles in compounding the drug product.
(4) The identity of the pharmacist(s) reviewing the drug product.
(5) The quantity of each component used in the drug product.
(6) The manufacturer and lot number of each component.
(7) The equipment used to compound the drug product.
(8) The internal reference number (lot number, batch number or control number).
(9) The beyond use date of the drug product.
(10) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of:

(1) The acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding according to compendial and other applicable requirements.
(2) The preparation, labeling, storage, and delivery of compounded drug products, according to compendial and other applicable requirements.
(3) Their efforts to assure the strength, quality, and integrity of drug products until dispensed to a patient or furnished to a prescriber for office use.

(c) All components used to compound drug products shall be obtained from reliable suppliers. Pharmacies shall maintain a certificate of purity or analysis for each lot, batch, delivery of all bulk chemicals used to compound drug products. Bulk chemicals that are considered dangerous drugs shall be obtained from a licensed wholesaler.

(d) All records required by this article shall be retained on the licensed premises in a readily retrievable form for a period of three years from the date of creation of the record.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005 Business and Professions Code.

§1735.3. Labeling

(a) In addition to labeling information required under Business and Professions Code Section 4076, the label of a drug product shall contain the generic name(s) of the principal active ingredient(s).

(b) Each prescription container shall be labeled with a statement that the drug product has been compounded by the compounding pharmacy. Where a pharmacy contracts with another pharmacy pursuant to Business and Professions Code section 4123, the container shall be labeled with the names of both the compounding and dispensing pharmacy.

(c) Where drug products are compounded into unit of use containers, the unit of use containers shall be labeled with the name(s) of the active component(s) [ingredients], concentration or strength, volume or weight, and a beyond use date.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4076, Business and Professions Code.

§1735.4. Policies and Procedures

(a) Pharmacies shall maintain a written policy and procedure manual for compounding that establishes: personnel involved in compounding; processes for education, training and competency evaluation of personnel involved in compounding; procurement procedures; methodologies for the formulation and compounding of drug products; protocols for facilities and equipment cleaning; and standard operating procedures for maintenance, operation, and personnel training.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge, who shall document the date when the annual review is completed.

(c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual shall also be included.

(d) The policy and procedure manual shall include written documentation of a plan for the recall of dispensed drug products where subsequent verification demonstrates the potential for adverse effects [patient harm]with continued use of the drug product.

(e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding a drug product shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.

(f) The pharmacist-in-charge shall establish policies and procedures to ensure that drug products have the strength indicated by the label.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4113, Business and Professions Code.

§1735.5. Facilities and Equipment

(a) Pharmacies shall provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug product, to also include, where applicable, certification of the facility/equipment.

(b) Equipment shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Equipment used in compounding drug products shall be calibrated prior to use to ensure accuracy. Documentation of calibration shall be recorded in writing.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.6. Training of Staff

(a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.

(b) The training of pharmacy personnel shall be documented and retained as part of an annual on-going competency evaluation process for the pharmacy personnel involved in compounding.

(c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug products prior to compounding any drug product.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.7. Quality Assurance

(a) Pharmacies shall maintain and document adherence to a written compounding quality assurance plan.

(b) The written quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate that the drug product meets the specified criteria of strength and quality.

(c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for drug products shall be retained and collated with the compounding record and master formula.

(d) The quality assurance plan shall also include a written process that describes and documents the action taken when a drug product fails to meet the minimum standards for quality, strength and integrity.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.8. Recall Notification

(a) A pharmacy shall recall a drug product that is misbranded, adulterated or has the potential for adverse effects [or potential patient harm] with continued use of the drug product. Within two (2) business days of the discovery of a drug product that is misbranded, adulterated or has the potential for adverse effects [or potential patient harm], the pharmacy shall notify the prescriber and the patient of the nature of the recall, the problem(s) identified and any recommended actions to assure patient safety.
(b) Any recall that is initiated by a pharmacy [where there is potential for patient harm] shall be reported, in writing, to the board within two (2) business days.

ATTACHMENT B

"Scott, George R"

01/07/2005 06:55 AM

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Dear Mr. Riches,

This is in response to the draft general compounding proposal sent electronically by Patricia Harris on September 28, 2004. We have reviewed the draft and have the following comment:

Part 2(f) of the draft states:

> (f) A pharmacy may contract with another pharmacy to compound non-sterile drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the following:
>
> (1) the name of the pharmacy that compounded the drug
> (2) the name of the pharmacy that dispensed the drug to the patient in addition
> (3) the information required by Business and Professions Code Section 4076.

As reflected in Compliance Policy Guide (CPG), section 460.200, FDA generally does not sanction compounding drugs for third parties to resell to individual patients. Consistent with this position, the agency believes that pharmacies normally should compound their own products. The agency likely would not exercise enforcement discretion towards a pharmacy that compounds drugs to be re-sold by other pharmacies, unless there is a specific need for this arrangement (e.g., difficult-to-compound products). In such cases, FDA would expect the compounding pharmacy to document a patient-specific need for the compounded product.

Regarding the specific language of Part 2(f), it is unclear to us if the phrase "pursuant to a prescription" means that the pharmacy compounding the product (contract pharmacy) receives the prescription, or a copy of the prescription, or whether the pharmacy dispensing the compounded product (contractee) receives the prescription. Because the contract pharmacy is not the same entity as the contractee, both entities should receive the prescription or a copy of the prescription.

FDA has advised some firms such as pharmacy outsourcers, which provide manipulated drugs as outside suppliers to hospital pharmacies for dispensing to patients, that they should register with FDA. Registration with FDA is not inconsistent with licensure under state pharmacy law.

Thank you for the opportunity to comment on your general compounding proposal. If you have any questions or need further information, please don't hesitate to contact me.

Sincerely,

George R. Scott, M.S., R.Ph.
Captain, US Public Health Service
Regulatory Operations Officer
Division of New Drugs and Labeling Compliance, HFD-310
Office of Compliance

ATTACHMENT C

ISSUE 1
Central Processing of Prescriptions by California Licensed Pharmacies

Scenario: Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

Discussion:
Under this scenario, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

ISSUE 2
California Central Prescription Processing Facility

Scenario: A prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

Discussion:
Business and Professions Code section 4071.1 authorizes a pharmacist to electronically enter a prescription or order into a pharmacy or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital.

California Code of Regulations, title 16, section 1793.7 authorizes a pharmacy to employ a non-licensed individual (clerk-typist) to enter prescription information into a computer system, generate a prescription label and to receive and request refill information. These functions must be performed under the direction of a pharmacist.

At least one central prescription processing facility in California has been licensed as a pharmacy. The reason for licensure as a pharmacy is two-fold. First, the prescriptions are faxed to the facility for central processing. Because there is a fax copy of the prescription, it has been reasoned that the facility must be licensed as a pharmacy to accept the faxed prescription document. (Cal. Code Regs., tit. 16, section 1717, subd. (e)). It can be argued that Business and Professions Code section 4051, subdivision (b)(2) authorizes the pharmacist to have access to the prescription, patient profile or other relevant medical information. This section doesn't require that this information be electronic only. However, does this central facility have the authority to maintain the faxed copy of the prescription record once it has been processed and the pharmacist has approved it for filling? Does the pharmacist? What happens to the faxed prescription document? What are the record-keeping requirements for each prescription recipient?

The second reason that this facility is licensed as a pharmacy is so that it can employ non-licensed pharmacy personnel to process prescriptions as authorized by California Code of Regulations, title 16, section 1793.7.

However, this central prescription processing facility doesn't dispense prescription drugs, so the question is raised whether this central facility is appropriately licensed as a "pharmacy." California pharmacy law defines a "pharmacy" in part as "an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded." (Bus. & Prof. Code, § 4037, subd. (a)). This definition also states that a pharmacy includes, but is not limited to, "any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." (*Ibid.*). Possession, storage, and sale of dangerous drugs or devices is therefore a central part, though not an explicitly necessary part, of the definition of a California "pharmacy."

California pharmacy law does not specifically define the scope of practice for the profession of pharmacy. That scope of practice has been defined in other sources. For instance, the National Association of Boards of Pharmacy in its *Model Act* defines the "Practice of Pharmacy" as: the interpretation, evaluation, and implementation of Medical orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Reviews, the Practice of Telepharmacy within and across state lines; Drug or Drug-Related research; the provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices and maintenance of proper records for them.

The issue before the Licensing Committee is whether or not the Board of Pharmacy

should license a "central prescription processing facility" located in California that does not dispense prescription drugs or devices as a "pharmacy."

Business and Professions Code section 4051, subdivision (b), provides that a pharmacist may perform cognitive services outside of a pharmacy as long as the pharmacist has access to the records. For discussion purposes, the committee may want to consider amending this section to require that the pharmacist in the central processing facility who is performing these services outside the pharmacy maintain the patient records or other patient specific information used in these activities in a readily retrievable form and provide those records to the board upon request. This would include all faxed prescription documents and other records. The proposal would require the pharmacist to maintain patient records similar to that of a prescriber and the patient records may be different than the patient profile maintained by the pharmacy.

The committee may also want to seek clarification from counsel as to whether the law needs to be amended to allow a pharmacist to use a "non-licensed" individual to assist in the processing of prescriptions at a central location.

Another alternative for consideration would be to develop a special license category for the central prescription processing center that is not designated as a "pharmacy," and therefore the facility isn't given the authority to compound, purchase, store, or dispense prescription drugs and devices.

ISSUE 3
Central Prescription Processing Facility and/or Call Center Located Outside of California

Scenario: A prescription originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

Discussion:
The out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

Therefore, does an out-of-state central prescription processing facility have the authority to process prescriptions for California patients? Is this authority increased if the review process is performed or overseen by a pharmacist licensed in California? Does a non-California licensed pharmacist have the authority to perform drug utilization review and/or other pharmacist's services for California patients? Also, what authority or ability does the Board of Pharmacy have to protect the public if the out-of-state pharmacist is unprofessional in providing pharmacist's care to California patients? What would be the record-keeping requirements for each prescription recipient?

Under current law, a California licensed nonresident pharmacy may perform all these services for California patients without requiring California licensure for the pharmacist.

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

ISSUE 4
Out-of-State Regional Call Center Database – Therapeutic Interchange

Scenario: A database for California pharmacies is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

Discussion

While the regional call center is licensed as a pharmacy in its domestic state, it doesn't appear to meet the definition of a California nonresident pharmacy (e.g., it does not ship, mail or deliver drugs into California). Based on the information provided, it is a California licensed pharmacist who makes the determination whether or not a therapeutic interchange is appropriate for the California patient and if so, then the California prescriber is contacted to approve the change. Can a pharmacy not licensed in California, such as this regional call center (e.g., licensed in Texas) maintain and make use of a pharmacy database for California patients?

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

ISSUE 5
Medication Therapy Management Programs Across State Lines

Consistent with the above scenarios, there is a provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments, medication "brown bag" reviews, formulating/monitoring/adjusting prescription treatment plans, patient education and training, collaborative drug therapy management, special packaging, refill reminders and other pharmacist related services.

Discussion
As pointed out in the comments provided by NABP to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, NABP was not clear on how states will view the provision of MTMP's across state lines. Similar to the situations presented above, California needs to decide how it wishes to address pharmacists not licensed in California providing MTM to California patients.

Another possible issue is whether California should alter, expand or refine its scope of practice and/or provisions dealing with collaborative practice/medication management to respond to the MMA and the existence of the MTM reimbursement protocols. As noted above, for example, the definition of "pharmacy" in the NABP *Model Act* addresses the propriety of collaborative practice and provision of drug management services explicitly.

SUMMARY

Issues for Consideration by the Licensing Committee

1. **Are any issues raised by inter-network pharmacy prescription processing?**

2. **How should a central processing prescription facility located in California that doesn't dispense prescription drugs or devices be regulated?**

    - **Should the facility be licensed as a pharmacy?**
    - **Should the facility be licensed as a "central processing prescription facility"?**
    - **Should such a facility be allowed?**
    - **Should the facility not be licensed, but require that the pharmacist maintain patient records for cognitive services? Should the pharmacist be allowed to use non-licensed personnel to assist in**

the processing of prescriptions as is currently authorized in a licensed (dispensing) pharmacy?

- **What are the record keeping requirements for each prescription recipient? Are the prescriptions being transmitted twice? First to the local pharmacy then to the central processing facility and then back to the dispensing pharmacy.**

3. **How should a central prescription processing facility located outside of California that processes prescriptions for California patients but doesn't dispense prescription drugs to California patients be regulated?**

    - **Should the facility be licensed as a nonresident pharmacy?**
    - **Should the facility be licensed as a nonresident "central processing prescription facility"?**
    - **Should an out-of-state facility be allowed to process prescriptions for California patients?**
    - **What are the record keeping requirements for each prescription recipient? Are the prescriptions being transmitted twice? First to the local pharmacy then to the central processing facility and then back to the dispensing pharmacy.**

4. **Can a pharmacist not licensed in California perform cognitive services (Medication Therapy Management) for California patients?**

    - **Can a pharmacist not licensed in California perform such services in a facility licensed in California as a nonresident pharmacy?**
    - **Should the pharmacist be licensed in California to perform such services for California patients?**

5. **Can an out-of-state pharmacy or call center (not licensed in California) maintain a central pharmacy database for California pharmacies and/or California patients? Who would have access to this database for California patients?**

ATTACHMENT D

State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: January 10, 2005

From: Debbie Anderson
Board of Pharmacy

Subject: Competency Committee Report

The Competency Committee has met two times since the October board meeting. The board transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. This committee develops and oversees administration of the California Pharmacist Jurisprudence Examination (CPJE).

Examination Statistics

The statistics for the board's examination process as of January 10, 2005, are as follows:

2,623 applications have been received by the board to take the CPJE

2,679 applications have been processed

2,130 individuals have been made eligible to take the licensure examinations

1,628 individuals have been verified to the NABP as qualified to take the NAPLEX for California including score transfers

227 individuals have been approved to retake the examinations.

1,316 individuals have become licensed as pharmacists since mid-June

The pass rate for the CPJE 85 percent.

Job Analysis

The board mailed out the job analysis surveys in December 2004 to approximately 3,000 pharmacists. The surveys were due to the board office on January 1, 2005. Approximately 1,200 surveys have been returned to the board

office. The board will mail the surveys to AMP for processing.

The results of the survey will be used to develop a content outline for future CPJE examinations. The new content outline will be developed by the committee in early 2005 and will be used in Spring 2005 to construct the CPJE.

Committee Restructure

The board approved the plan to split the examination development duties currently performed by the Competency Committee into the two committees including one group of item writers and another group that will perform item selection, performance review and scoring. The Competency Committee is awaiting the responses from the article in the January 2005 newsletter soliciting new members.

Release of Exam Results

Examination statistics are released once a year for state reporting based on the fiscal year. The board is working with the examination consultant in finalizing a regular schedule for releasing examination statistics. The board will try to release examination statistics one additional time each year so the schools of pharmacy can access the performance of their graduates on the examination.

Competency Committee Update

Board President Stanley Goldenberg appointed Dr. Frances Wong as Chairperson to the Competency Committee. Dr. Wong replaces Dr. RoseAnn Jankowski who has served as the Chairperson since 2001 and on the committee since 1994.

Dr. Wong is an Associate Professor of Clinical Pharmacy at the USC School of Pharmacy. Her practice site is at USC University Hospital where she is a clinical pharmacist in the Medical and Cardiac Intensive Care Unit. Dr. Wong also coordinates the reporting of Adverse Drug Reactions for the hospital. In addition, she teaches 4th year pharmacy students who are rotating through the hospital on their Acute Care Medicine / Hospital Practice clerkships. Dr. Wong has been with USC for 12 years. Dr. Wong has served on the Competency Committee since 1998.

ATTACHMENT E

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: December 1, 2004

TIME: 10:00 a.m. – 12:30 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019

Workgroup Members: Ken Schell, Pharm.D., Chair

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General

Call to Order/Introductions

The meeting was called to order at 10:00 a.m. Meeting participants introduced themselves.

It was reported that this was the final meeting of the workgroup. A draft proposal on general compounding was provided. It contained proposed statutory and regulatory language to define general compounding, which currently is not defined in pharmacy law. It also establishes the requirements for all pharmacies that compound drug products. It requires that the pharmacist have a professional relationship with both the prescriber and the patient. The proposal also addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug product, and requirements for facilities and equipment. The proposal also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications. One section that will be added to the proposal will be a recall process should the compounded drug product be misbranded, adulterated, or potential to harm a patient.

Dr. Schell acknowledged the participants and thanked them for their commitment and involvement. While the workgroup was initially formed in part to respond to a request from the Department of Health Services (DHS) to identify the criteria used by the board to determine

when a compounding pharmacy should be considered a manufacturer, it was the board's goal to work with the compounding profession in trying to respond to the request from DHS as well as to identify "gaps" in pharmacy law related to pharmacy compounding, and to address them.

Dr. Schell stated that the purpose of this final meeting was to review the proposed draft, discuss questions and comments, and to revise the draft accordingly. In the afternoon, Dr. Schell would present the proposal to the Licensing Committee with the request that the committee recommend to the Board of Pharmacy that it support the general compounding proposal. The board will review this request at its January meeting. If the board approves the recommendation, then the intent is to sponsor legislation in 2005. Dr. Schell explained that throughout this process, interested parties have the opportunity to comment on the proposal.

General Compounding Proposal

Board Supervising Inspector Dennis Ming and Deputy Attorney General Joshua Room reviewed the general compounding proposal. The workgroup discussed the proposal and comments were noted. It was suggested that the definition be clarified regarding the reconstitution of a drug product according to the manufacturers' directions, the use of flavoring and whether the compounding of over-the-counter (OTC) products requires a prescription. (It is the board's position that any compounding by a pharmacy requires a prescription.)

Another concern raised was the proposed amendment to Business and Professions Code section 4123 regarding the authority for a pharmacy to contract with another pharmacy to a compound a drug. The language would allow for a pharmacy to contract with another pharmacy for the purpose of delivering a compounded drug product to another pharmacy pursuant to a prescription, provided that the drug is not compounded prior to the receipt of the prescription.

Many of the workgroup participants recommended that the proposed language allow for the contract pharmacy to compound drug products in anticipation of receiving a prescription. It was argued especially in the hospital setting. It was stated that since the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) adopted the newly revised USP 797 on sterile compounding, many pharmacies plan to centralize their compounding facilities and for good patient care; pharmacies must have the ability to compound in anticipation of some prescriptions in order to furnish the need medication timely.

The workgroup reviewed the proposal and provided comments.

Adjournment

Dr. Schell thanked the participants for attending. He stated that a copy of the revised proposal will be provided to the workgroup members in early January. Dr. Schell adjourned the meeting at 12:30 p.m.

ATTACHMENT F

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE: December 1, 2004

TIME: 1:30 p.m. – 3:00 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
Dana Winterrowd, Legal Counsel

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 1:30 p.m. She explained that committee members John Tilley and Richard Benson were unable to attend the meeting.

Workgroup on Compounding – General Compounding Proposal

Dr. Schell reported that the Workgroup on Compounding was initially formed in part to respond to a request from the Department of Health Services – Food and Drug Branch to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer. The goal was to work with the compounding profession to respond to this request as well as identify and address "gaps" in pharmacy law related to pharmacy compounding. At each workgroup meeting, there have been over 30 participants that have provided valuable input into the process.

Dr. Schell explained that at the September meeting a concept draft to regulate general compounding by pharmacies was presented and discussed. Based on the discussion and the comments that were provided, proposed statutory and regulatory amendments were drafted for

the workgroup's review. The Workgroup on Compounding met on December 1st (prior to the Licensing Committee meeting) for final review and discussion of the proposal. It was noted that the workgroup members would have the opportunity to address any concerns regarding the proposal to this committee and ultimately to the board.

Dr. Schell explained that the proposal that is being recommended for the Licensing Committee's consideration includes a definition of compounding, which currently is not defined in pharmacy law. It requires that the pharmacist have a professional relationship with both the prescriber and the patient. The proposal also addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug product, and requirements for facilities and equipment. The proposal also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications.

Dr. Schell reiterated that at the September workgroup meeting, there was considerable discussion regarding the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s). As stated previously, one of the initial requests from DHS was for the board to identify the criteria it uses to determine when a compounding pharmacy would be considered a manufacturer. While one of the workgroup subcommittees updated the list of factors that the board developed many years ago, board counsel explained that the proposed "factors" for distinguishing compounding from manufacturing would at best be considered "guidelines," and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

Further, counsel advised that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer.

While compounding is included in the definition of manufacturing, a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner).

Therefore, Dr. Schell concluded that based on counsel's advice the Board of Pharmacy's priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. This proposal provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed statutory and regulatory changes relating to general compounding. The statutory changes would be introduced in 2005 and upon successful enactment; the regulation proposal would be pursued.

Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients

Executive Officer Patricia Harris explained that she prepared a background document for the Licensing Committee that gave an overview on the many issues and questions that the Board of Pharmacy has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin discussion on how the board should address these many issues that don't fit the traditional statutory definition of pharmacy practice and the independent practice of pharmacists as health care providers.

The background document provided for five issues. The first issue addressed the central processing of prescriptions by California licensed pharmacies. In this situation, Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

In this situation, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

The Licensing Committee didn't have an issue with this situation.

In the second example, a prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

At least one central prescription processing facility in California has been licensed as a pharmacy. The reason for licensure as a pharmacy is two-fold. First, the prescriptions are faxed

to the facility for central processing. Because there is a fax copy of the prescription, it has been reasoned that the facility must be licensed as a pharmacy to accept the faxed prescription document. (Cal. Code Regs., tit. 16, section 1717, subd. (e)). It can be argued that Business and Professions Code section 4051, subdivision (b)(2) authorizes the pharmacist to have access to the prescription, patient profile or other relevant medical information. This section doesn't require that this information be electronic only. However, does this central facility have the authority to maintain the faxed copy of the prescription record once it has been processed and the pharmacist has approved it for filling? Does the pharmacist? What happens to the faxed prescription document? What are the record-keeping requirements for each prescription recipient?

The second reason that this facility is licensed as a pharmacy is so that it can employ non-licensed pharmacy personnel to process prescriptions as authorized by California Code of Regulations, title 16, section 1793.7.

However, this central prescription processing facility doesn't dispense prescription drugs, so the question is raised whether this central facility is appropriately licensed as a "pharmacy." California pharmacy law defines a "pharmacy" in part as "an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded." (Bus. & Prof. Code, § 4037, subd. (a)). This definition also states that a pharmacy includes, but is not limited to, "any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." (*Ibid.*). Possession, storage, and sale of dangerous drugs or devices are therefore a central part, though not an explicitly necessary part, of the definition of a California "pharmacy."

California pharmacy law does not specifically define the scope of practice for the profession of pharmacy. That scope of practice has been defined in other sources. For instance, the National Association of Boards of Pharmacy in its *Model Act* defines the "Practice of Pharmacy" as: the interpretation, evaluation, and implementation of Medical orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Reviews, the Practice of Telepharmacy within and across state lines; Drug or Drug-Related research; the provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices and maintenance of proper records for them.

The issue before the Licensing Committee is whether or not the Board of Pharmacy should license a "central prescription processing facility" located in California that does not dispense prescription drugs or devices as a "pharmacy."

The third scenario is related to a prescription that originates in California. It is sent

electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

It was noted that the out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

Questions that need to be considered are: Does an out-of-state central prescription processing facility have the authority to process prescriptions for California patients? Is this authority increased if the review process is performed or overseen by a pharmacist licensed in California? Does a non-California licensed pharmacist have the authority to perform drug utilization review and/or other pharmacist's services for California patients? Also, what authority or ability does the Board of Pharmacy have to protect the public if the out-of-state pharmacist is unprofessional in providing pharmacist's care to California patients? What would be the record-keeping requirements for each prescription recipient?

Under current law, a California licensed nonresident pharmacy may perform all these services for California patients without requiring California licensure for the pharmacist.

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

The fourth example that was presented was about a database for California pharmacies that is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

While the regional call center is licensed as a pharmacy in its domestic state, it doesn't appear to meet the definition of a California nonresident pharmacy (e.g., it does not ship, mail or deliver drugs into California). Based on the information provided, it is a California licensed pharmacist who makes the determination whether or not a therapeutic interchange is appropriate for the California patient and if so, then the California prescriber is contacted to approve the change. Can a pharmacy not licensed in California, such as this regional call center (e.g., licensed in Texas) maintain and make use of a pharmacy database for California patients?

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

The last situation that was discussed is a new provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments, medication "brown bag" reviews, formulating/monitoring/adjusting prescription treatment plans, patient education and training, collaborative drug therapy management, special packaging, refill reminders and other pharmacist related services.

It was noted in the comments provided by the National Association of Boards of Pharmacy (NABP) to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, NABP was not clear on how states will view the provision of MTMP's across state lines. Similar to the situations presented above, California needs to decide how it wishes to address pharmacists not licensed in California providing MTM to California patients.

Another possible issue is whether California should alter, expand or refine its scope of practice and/or provisions dealing with collaborative practice/medication management to respond to the MMA and the existence of the MTM reimbursement protocols. As noted above, for example, the definition of "pharmacy" in the NABP *Model Act* addresses the propriety of collaborative practice and provision of drug management services explicitly.

There was considerable discussion by the Licensing Committee about the changes to pharmacy practice and how these many changes don't fit the traditional definition of pharmacy. The committee agreed to address these issues through its committee meetings in 2005.

Status on the Licensing of Pharmacists in California

The Assistant Executive Officer Virginia Herold reported that the Board of Pharmacy transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. She reported that as of November 19, 2004, the board has received over 2,500 applications to take the California license examinations, and since June 2004, over 1,200 applicants have been licensed as pharmacists. She also noted that the pass rate for the California Pharmacy Jurisprudence Examination (CPJE) is 85%.

Ms. Herold stated that the job analysis survey for the CPJE was mailed 3,000 pharmacists. The job analysis is done every 5 years and its purpose is to develop the content outlines of the CPJE. Pharmacists who complete the survey will be awarded continuing education credit for their participation.

Implementation of AB 2682 (Chapter 887, Statutes of 2004) Regarding the Licensure of Wholesalers and Nonresident Wholesalers

Ms. Harris reported that Assembly Bill 2682, signed by Governor Schwarzenegger on September 29, 2004, makes changes to several Business and Professions Code sections specific to the licensing requirements for wholesalers located outside of California who ship, mail or delivers dangerous drugs or devices into California. Because of the significant changes, the requirements will be phased in over the next two years. The following is a brief description of these changes.

- B & P 4043 – Changes that the name of a wholesaler shipping drugs into California from an out-of-state distributor to a nonresident wholesaler. This change is effective January 1, 2006.
- B & P 4161 – Requires any out-of-state distributor who ships, mails, or delivers dangerous drugs or devices into California to be licensed with the board. Previously any business that that shipped into California to another California licensed wholesaler was exempt from obtaining a California license. This changed is effective January 1, 2005. Effective January 1, 2006, B & P 4161 is again amended to change the name from out-of-state distributor to nonresident wholesaler and to change the title of "exemptee-in-charge" to "designated representative-in-charge."
- B & P 4162.5 – Requires an applicant for licensure or renewal to submit a surety bond of $100,000 for each nonresident wholesaler site licensed or to be licensed. The board may accept a surety of bond of $25,000 if the annual gross receipts of the previous tax year, as a nonresident wholesale is $10,000,000 or less. This section takes effect January 1, 2006.

To facilitate the implementation of these changes, board staff, along with DAG Joshua Room, has reviewed and revised the application forms, requirements and processes for both the wholesaler and nonresident wholesalers. It is anticipated that the new forms will be available on the board's website by mid-December.

Committee Meeting Dates for 2005

The Licensing Committee set its meeting dates and locations for 2005: March 16th – Oakland, June 15th – Burbank, September 21st – Oakland and December 14th – Burbank.

Adjournment

Licensing Committee Chair Ruth Conroy adjourned the meeting at 3:00 p.m.

ATTACHMENT G

Licensing Committee

2004-2005
Second Quarter Report
October 1, 2004 – December 31, 2004

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2005.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system has been implemented.

Tasks:

1. **Review 100 percent of all applications within 7 working days of receipt.**

   Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:				**Average Days to Process:**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	369*	185**			23	24		
Pharmacist (initial licensing)	783*	268**			3	7		
Pharmacy Intern	733*	464**			10	7		
Pharmacy Technicians	1625*	889**			5-10	15-20		
Foreign Graduates								
Pharmacies	100	95			6	9		
Non-Resident Pharmacy	20	16			22	16		
Wholesaler	19	34			39	4		
Veterinary Drug Retailer	0	1			0	0		
Exemptee	140	91			8	12		
Out-of-State Distributor	30	23			7	18		
Clinics	62	27			7	6		
Hypo Needle & Syringe	9	6			1	8		
Sterile Compounding	20	14			2	4		

* Denotes September 2004 information has been added since the First Quarter report.
**Denotes October and November 2004 information available at time of report development.

2. **Process 100 percent of all deficiency documents within 3 working days of receipt.**

Average days to process deficiency:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	3-7	5-10		
Pharmacist (initial licensing)	3-7	5-10		
Pharmacy Intern	10	7		
Pharmacy Technicians	5-7	7		
Foreign Graduates				
Pharmacies	9	3		
Non-Resident Pharmacy	10	1		
Wholesaler	9	8		
Veterinary Drug Retailer	0	0		
Exemptee	3	4		
Out-of-State Distributor	11	10		
Clinics	7	2		
Hypo Needle & Syringe	5	1		

3. **Make a licensing decision within 3 working days after all deficiencies are corrected.**

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	1-2	1-2		
Pharmacist (initial licensing)	1-2	1-2		
Pharmacy Intern	5	3-5		
Pharmacy Technicians	5	5		
Pharmacies	4	2		
Non-Resident Pharmacy	3	1		
Wholesaler	3	3		
Veterinary Drug Retailer	0	0		
Exemptee	2	12		
Out-of-State Distributor	4	3		
Clinics	4	1		
Hypo Needle & Syringe	6	1		

4. **Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.**

	Q1	Q2	Q3	Q4
Pharmacist	762*	389		
Pharmacy Intern	467*	577		
Pharmacy Technician	1743*	1092		
Foreign Graduate	N/A	N/A		
Pharmacies	121	79		
Non-Resident Pharmacy	11	10		
Wholesaler	25	14		
Veterinary Drug Retailer	3	0		
Exemptee	122	106		
Out-of-State Distributor	25	23		
Clinics	53	24		
Hypo Needle & Syringe	12	6		
Sterile Compounding	13	16		
* Denotes September 2004 information has been added since the First Quarter report.				

5. **Withdrawn licenses to applicants not meeting board requirements.**

	Q1	Q2	Q3	Q4
Pharmacy Technician	11	0		
Pharmacies	15	1		
Non-Resident Pharmacy	13	1		
Clinics	28	3		
Sterile Compounding	2	5		
Exemptees	0	32		
Hypo Needle & Syringe	0	3		
Out-of-State Distributor	0	8		
Wholesaler	0	4		

Objective 2.2: **Implement at least 50 changes to improve licensing decisions by June 30, 2005.**

Measure: **Number of implemented changes.**

Tasks:

1. **Review Pharmacist Intern Program.**

9/04 *Governor signed SB 1913 that contained new intern provisions to become effective 1/05.*

9/04 *Licensing Committee recommended changes to 1728 to implement SB 1913.*

9/04 *Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.*

9/04 *Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*

12/04 *Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*

2. Implement changes to the Pharmacy Technician Program.

1/04 *a. Use PTCB as a qualifying method for registration. – Completed.*

1/04 *b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology. – Completed.*

9/04 *c. Eliminate clerk-typist from pharmacist supervisory ratio. Completed – regulation approved by OAL, change effective 10/3/04.*

9/04 *Enforcement Committee recommended technical changes to the regulatory requirements for pharmacy technicians.*

10/04 *Board approved the recommendation and will sponsor legislation in 2005.*

3. Administer a pharmacist licensure exam more than twice a year.

3/04 *Completed – CA applications began taking the NAPLEX and CPJE.*

9/04 *826 California applicants have taken the NAPLEX and 1,006 have taken the CPJE since July 1, 2004.*

1/05 *1,240 California applicants have taken the NAPLEX and 1,335 have taken the CPJE since July 1, 2004.*

4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.

5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.

6. **Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.**

8/04 *Competency Committee met for two days and developed questions as well as the job analysis.*

9/04 *Competency Committee met for two days and developed questions.*

9/04 *Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).*

10/04 *Competency Committee met for two days and developed questions.*

11/04 *Job analysis will be released.*

12/04 *Job analysis released to 3,000 pharmacists.*

1/05 *Competency Committee met for two days and developed questions.*

7. **Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.**

6/04 *Completed*

9/04 *OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.*

9/04 *Reported that 13 sterile compounding licensed have been issued since July 1, 2004.*

1/05 *Reported that 29 sterile compounding licenses have been issued since July 1, 2004.*

8. **Issue temporary permits whenever change of ownership occurs.**

9/04 *1st Quarter – 22 temporary permits issued.*

1/05 *2nd Quarter – 29 temporary permits issued.*

9. **Establish means for licensee to renew permits on line.**

8/04 *Submitted Applicant Tracking System (ATS) report to the department.*

11/04 *Met with the department to discuss conversion to ATS and department prioritization.*

10. **Implement Changes to Facilities Licensure Requirements**

9/04 *Governor signed SB 1913 that included application requirements for all applicants.*

9/04 *Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.*

9/04 *Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.*

1/05 *New application forms are available for nonresident wholesalers.*

11. Review the Ownership of Pharmacies

7/04 *Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.*

12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.

7/04 *Draft report provided to the board.*

9/04 *Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).*

9/04 *Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.*

12/04 *Report provided to the Legislature.*

13. Evaluate application requirements for all licenses.

9/04 *Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.*

9/04 *Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).*

9/04 *Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.*

9/04 *Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

9/04 *Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.*

9/04 *Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.*

10/04 *Board approved statutory proposal to eliminate the rules of professional conducted required for each application and omnibus changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

12/04 *Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*

14. Review the law regarding the educational requirements of graduates from foreign pharmacy schools.

9/04 *Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.*

9/04 *Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*

9/04 *Sent a letter to all pending foreign graduates advising of law change and suspending application process.*

12/04 *Sent letter to all foreign graduate exam applicants not certified about revised exam eligibility status.*

15. Review the law regarding continuing education (CE) requirements for pharmacists.

7/04 *Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*

9/04 *Licensing Committee recommended changes to the CE statute to relocate from regulation the 30 hour requirement, to exempt all newly licensed pharmacist from CE requirements for two years and to renew the pharmacists license as "inactive" when a pharmacist fails to certify their CE credits.*

9/04 *Licensing Committee recommended revisions to the CE regulations.*

10/04 *Board approved recommended statutory and regulatory revisions to CE requirements.*

16. Review the license of city and county jails and juvenile facilities.

8/04 *Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.*

Objective 2.3:	**Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.**	
Measure:	**Number of public policy initiatives evaluated.**	
Tasks:	**1.**	**Explore the need to regulate pharmacy benefit managers.**
10/03		*Board concluded not to regulate PBMs.*
9/04		*Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.*
	2.	**Explore the need to regulate drugs labeled for "veterinary use only."**
9/03		*SB 175 was introduced and signed (Chaptered 250, Statutes 2003).*
1/04		*Completed.*
	3.	**Explore the importation of drugs from foreign countries.**
7/04		*Discussed at July Board meeting.*
9/04		*Discussed at September Enforcement Committee meeting.*
9/04		*Governor vetoed SB 1449 which would have required the board to approve Web sites for Canadian pharmacies.*
10/04		*Discussed at October board meeting.*
12/04		*Discussed at December Enforcement Committee meeting.*
12/04		*HHS released its report of the Task Force on Drug Importation.*

4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.

9/04 *OAL approved regulation change and will take effect 10/22.*

10/04 *Completed.*

5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding

9/04 *Held third meeting of workgroup on compounding – proposed draft concept on general compounding.*

6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)

7/04 *Protocol on Web site.*

7/04 *Board approved regulation on protocol.*

9/04 *Regulation submitted to OAL for approval.*

11/04 *OAL approved regulation, which became effective 12/04.*

7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.

9/04 *Governor signed SB 1913 that provides authority.*

8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.

4/04 *Board approved waiver for two years.*

9. Development of Proposal for Pharmacist Performing DUR, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for CA patients.

12/04 *Licensing Committee discussed concepts related to proposal.*

Objective 2.4:	**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.**
Measure:	**Percentage of cashiered application and renewal fees within 2 working days.**
Tasks:	**1. Cashier application fees.**
9/04	*1st Quarter - The average processing time for processing new application fees is 2-3 working days.*
1/05	*2nd Quarter - The average processing time for processing new application fees is 2-3 working days.*
	2. Cashier renewal fees.
9/03	*The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.*
8/04	*Held interviews for renewal cashier because hiring freeze was lifted.*
9/04	*1st Quarter - Average processing time for central cashiering is 2-3 weeks.*
10/04	*Filled vacancy for renewal cashier.*
1/05	*2nd Quarter – Average processing time for central cashiering is 1-2 weeks.*
Objective 2.5:	**Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.**
Measure:	**Percentage response for verifying licensing information within 5 working days.**
Tasks:	**1. Respond to requests for licensing verification.**
9/04	*1st Quarter – Processed 227 license verifications.*
1/05	*2nd Quarter – Processed 208 license verifications.*
Objective 2.6:	**Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**
Measure:	**Percentage of licensing records changes within 5 working days**
Tasks:	**1. Make address and name changes.**

9/04 *1st Quarter – Processed 2,478 address changes.*

1/05 *2nd Quarter – Processed 1, 557 address changes.*

2. Process discontinuance of businesses forms and related components.

9/04 *1st Quarter – Processed 26 discontinuance- of-business forms. Processing time is 44 days.*

1/05 *2nd Quarter – Processed 61 discontinuance- of-business forms. Processing time is 40 days.*

3. Process changes in pharmacist-in-charge and exemptee-in-charge.

9/04 *1st Quarter – Processed 421 pharmacist-in-charge changes. Average processing time is 23 days. Processed 12 exemptee-in-charge changes. The average processing time is 2 days.*

1/05 *2nd Quarter – Processed 395 pharmacist-in-charge changes. Average processing time is 25 days. Processed 6 exemptee-in-charge changes. The average processing time is 2 days.*

4. Process off-site storage applications.

9/04 *Processed 33 off-site storage applications.*

1/05 *Processed 15 off-site storage applications.*

5. Process change-of-permit applications.

9/04 *1st Quarter – Processed 142 applications. Average processing time is 25 days.*

1/05 *2nd Quarter – Processed 219 applications. Average processing time is 15 days.*

Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	139	109	121	109	76								554
Pharmacist (initial licensing applications)	265	233	285	156	112								1051
Intern pharmacist	59	257	417	363	101								1197
Pharmacy technician	453	525	647	534	355								2514
Foreign educated pharmacists (evaluations)	11	57	n/a	n/a	n/a								68
Pharmacy	27	41	32	34	26	20							180
Sterile Compounding	4	12	4	4	4	6							34
Clinics	28	21	13	8	10	9							89
Hospitals	5	2	6	10	3	2							28
Nonresident Pharmacy	8	9	3	10	2	4							36
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	2	2	5	4	0	2							15
Out of State Distributor	11	11	8	5	3	15							53
Wholesalers	8	5	6	2	9	23							53
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	1							1
Exemptees	55	29	56	40	33	18							231
Issued													
Pharmacist	307	229	226	169	129	91							1151
Intern pharmacist	63	178	226	274	230	73							1044
Pharmacy technician	672	408	663	506	353	233							2835
Pharmacy	28	36	49	23	20	29							185
Sterile Compounding	4	7	2	5	4	7							29
Clinics	15	15	23	15	7	2							77
Hospitals	4	2	2	2	3	2							15
Nonresident Pharmacy	4	4	3	5	4	3							23
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	7	2	3	0	5	1							18
Out of State Distributor	4	13	8	7	8	8							48
Wholesalers	6	5	14	1	7	6							39
Veterinary Food-Animal Drug Retailer	0	3	0	0	0	0							3
Exemptees	42	52	28	45	38	23							228

Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	200	76	69	179	101	47							47
Intern pharmacist	u/a	u/a	83	u/a	u/a	66							66
Pharmacy technician	u/a	u/a	u/a	u/a	u/a	u/a							u/a
Foreign educated pharmacists (evaluations)	n/a	n/a	n/a	n/a	n/a	n/a							n/a
Pharmacy	71	69	52	63	69	60							60
Sterile Compounding	43	48	50	49	49	48							48
Clinics	61	67	57	50	53	60							60
Hospitals	10	8	12	20	20	20							20
Nonresident Pharmacy	33	29	29	34	32	33							33
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	3	3	5	9	4	5							5
Out of State Distributor	47	45	50	48	43	50							50
Wholesalers	27	27	19	20	22	39							39
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	1							1
Exemptees	180	157	185	97*	92	87							87
Change of Pharmacist-in-Charge													
Received	183	229	156	151	122	111							952
Processed	141	175	105	164	119	112							816
Pending	214	268	319	306	309	308							308
Change of Exemptee-in-Charge													
Received	4	4	3	3	3	1							18
Processed	4	5	3	1	3	1							17
Pending	1	0	0	2	0	0							0
Change of Permits													
Received	30	86	60	61	60	44							341
Processed	24	69	49	90	61	68							361
Pending	139	156	167	138	137	113							113
Discontinuance of Business													
Received	11	15	17	18	14	13							88
Processed	0	26	0	25	1	35							87
Pending	16	21	38	31	44	22							22

Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

Renewals Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist	1031	3278	1249	1182	1067								7807
Pharmacy technician	1339	3089	1763	1692	1529								9412
Pharmacy	652	609	862	508	284								2915
Sterile Compounding	12	12	11	22	4								61
Clinics	49	149	55	50	49								352
Nonresident Pharmacy	19	32	11	18	4								84
Hypodermic Needle and Syringes	16	18	21	22	18								95
Out of State Distributor	18	56	22	23	20								139
Wholesalers	28	98	22	37	28								213
Veterinary Food-Animal Drug Retailer	1	5	1	2	0								9
Exemptees	113	348	119	122	126								828

*hand count

ATTACHMENT H

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Report on the Requirement that Candidates Failing the California Pharmacist Licensure Examination Four Times Must Obtain Additional Education in Pharmacy

Pursuant to California Business and Professions Code section 4200.1, the California State Board of Pharmacy is pleased to provide the following report detailing the impact of requiring candidates for pharmacist licensure who fail the licensure examination four times to take remedial education before they can retake the licensure examination.

The board is required to submit this report after June 1, 2004, and before December 31, 2004.

Background:

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times have been required to take 16 units of education in pharmacy from a school of pharmacy approved by the Accreditation Council for Pharmacy Education (formerly known as the American Council on Pharmaceutical Education). This provision was set to be repealed January 1, 2005. However, subsequent legislation enacted in 2004 (Senate Bill 1913, Senate Business and Professions Committee, Chapter 695) extended the sunset date for this provision until January 1, 2008.

The board sponsored the initial requirement for candidates to take remedial education after four attempts at passing the pharmacist licensure examination for various reasons. One reason was to remove a number of applicants from the licensure examination who had repeatedly failed the examination. For example, there were several applicants who had taken the examination more than 25 times (the examination was given twice a year until January 2004). A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The requirement to take remedial education took effect July 1, 1998. To implement the statutory provisions, the board adopted a regulation that took effect November 4, 1998 (California Code of Regulations, Title 16, section 1725). This regulation specifies that the remedial education of 16 units must be taken in a school of pharmacy approved by the American Council on Pharmaceutical Education (which in 2003 became known as the Accreditation Council for Pharmacy Education) or a school recognized by the board. The ACPE accredits schools of pharmacy in the United States. The Board of Pharmacy never separately recognized any school.

From July 1, 1998 until January 1, 2004, the board gave 10 examinations (January and June, 1999 - 2003). Each of these examinations was written and graded exclusively for California by the California State Board of Pharmacy. The examination was developed by a team of 22 subject matter experts, under the guidance of a psychometric consulting firm selected to assure that the examination met all required components for job relevancy and validity. Throughout this period, the licensure examination was comprised of two sections: a 300-point multiple-choice examination and a 100-point, short answer section. The multiple-choice examination was administered in two three-hour segments and the short answer segment was administered in a three-hour segment. Each examination was administered over a two-day period, in one location (Oakland or San Mateo), and given in a paper and pencil format.

In January 2004, there was a substantial change in the California pharmacist licensure examination made by SB 361 (Figueroa, Chapter 539, Statutes of 2003). The new provisions require the use of the National Association of Boards of Pharmacy Examination (called NAPLEX) and a second, California-specific and jurisprudence examination. Both are multiple-choice examinations and are given via computer, six days per week at testing centers nationwide. Testing began under the new format in late March 2004.

Because of the substantial difference in the licensure examinations after January 1, 2004, this report on examination performance uses data only from the prior form of the examination (that was given between 1999 and 2003).

The board will again report on the effect of requiring remedial education under the new examination structure in another report to the Legislature. Amendments made in 2004 to California Business and Professions Code section 4200.1 to extend the remedial education requirement also direct that the board report on all examinations given between January 1, 2004 and July 1, 2006, in a report due before September 1, 2006.

Data:

The board is required to report on four components. Each of these components is individually discussed below. For ease of presentation the required component appears in bold.

1. **The number of applicants taking the examination and the number who fail the examination for the fourth time.**

   Approximately 2 percent of all exam attempts during the five-year study period were made by those who failed the licensure examination the fourth time they took it. Table 1 displays this data by the date of exam administration.

Table 1

EXAM	TOTAL CANDIDATES	FOUR-TIME FAILERS	PERCENT
June 2003	1,284	12	0.9 percent
Jan. 2003	675	15	2.2 percent
June 2002	1,156	6	0.5 percent
Jan. 2002	536	21	3.9 percent
June 2001	1,155	12	1.0 percent
Jan. 2001	601	18	3.0 percent
June 2000	1,065	11	1.0 percent
Jan. 2000	537	14	2.6 percent
June 1999	950	9	0.9 percent
Jan. 1999	508	28	5.5 percent
	8,467 exam attempts	146 failed 4-times	1.7 percent

2. **The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California and the number of these applicants who are accepted in to the pharmacy education program.**

In California there were four schools of pharmacy during this period. Only one school, the University of Southern California, developed a program for students who failed the California examination four times. This was a special program offered in the fall of 1998 through spring of 2001. During this time, 63 individuals enrolled in the program and 49 completed the 16 units at USC.

Because admission to pharmacy schools is not within the board's jurisdiction or control, the board cannot report data on how many applicants applied to USC or other schools of pharmacy in California to complete the 16 units of pharmacy education, and were denied admission or decided not to attend.

3. **The number of applicants who, after failing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.**

As stated above, because admission to pharmacy schools is not within the board's jurisdiction or control, the board cannot report on how many applicants applied to any schools of pharmacy nationwide to undertake supplemental pharmacy education. The board is only aware of those candidates who completed the 16 units and reapplied to retake the examination in California.

The first group of "requalifers" (those who completed the 16 units of education and were again eligible to take the examination) were able to retake the California

pharmacist examination beginning in January 2000. The number of candidates who passed the licensure examination following completion of this training is provided in parentheses (Table 2).

Table 2

Examination	California Schools Only Number Requalified	All Other Schools Number Requalified	Total
June 2003	2 (1)	13 (2)	15 (3)
January 2003	8 (1)	9 (3)	17 (4)
June 2002	10 (1)	5 (1)	15 (2)
January 2002	6 (0)	5 (1)	11 (1)
June 2001	19 (4)	7 (0)	26 (4)
January 2001	15 (0)	4 (1)	16 (1)
June 2000	24 (3)	4 (1)	27 (4)
January 2000	26 (2)	3 (1)	29 (3)
			156 (22)

A total of 22 individuals of the156 individuals who requalified to take the examination, passed the licensure examination during this period of study. This is 14 percent of those who requalified and retook the examination. (Note: 12 individuals who had failed the examination four or more times before 1999 completed remedial education and requalifed to take the examination during the period of study.)

4. **To the extent possible, the school and country from which applicants graduate and the comparative pass/fail rates on the examination in relation to the school and country.**

There are two tables to display these data. The first table (Table 3) displays pass and fail statistics for candidates from each US school of pharmacy during the five-year study period.

Table 4 displays pass and fail statistics by the country where the candidate completed pharmacy school.

Summary:

Between January 1999 and June 2003, the California State Board of Pharmacy administered 10 unique pharmacist licensure examinations a total of 8,467 times. The overall passing rate during this period was 53.4 percent. Because most individuals who failed the examination could retake the examination at a later time, fewer than 8,467 individuals actually took the examinations. During this period, 1.7 percent of the examinations taken were by applicants who failed the examination on the fourth attempt.

There were more than 4,500 individuals who passed the pharmacist licensure examination during these five years.

A total of 156 individuals requalifed to take the pharmacist licensure examination during this period by completing 16 units of study in a school of pharmacy. A total of 22 individuals of these 156 individuals passed the licensure examination during the study period. This is 14 percent of those who requalified and retook the examination.

Pharmacist Licensure Examination
Pass/Fail Rates by School of Pharmacy

U.S. Schools of Pharmacy *	Pass		Fail		Total
	Number	Percent	Number	Percent	
Auburn	8	44.4%	10	55.6%	18
Samford (Alabama)	5	16.1%	26	83.9%	31
University of Arizona	34	46.6%	39	53.4%	73
University of Arkansas	5	35.7%	9	64.3%	14
U.C.S.F.	564	77.9%	160	22.1%	724
University of Pacific	915	71.6%	363	28.4%	1278
U.S.C.	780	78.3%	216	21.7%	996
University of Colorado	39	40.2%	58	59.8%	97
University of Connecticut	9	52.9%	8	47.1%	17
Howard University	8	23.5%	26	76.5%	34
Florida A & M	17	45.9%	20	54.1%	37
University of Florida	9	50.0%	9	50.0%	18
Mercer	18	50.0%	18	50.0%	36
University of Georgia	35	43.8%	45	56.3%	80
Idaho State University	35	53.0%	31	47.0%	66
University of Illinois (Chicago)	58	43.3%	76	56.7%	134
Butler University	18	72.0%	7	28.0%	25
Purdue University (Indiana)	21	29.2%	51	70.8%	72
Drake University (Iowa)	44	48.4%	47	51.6%	91
University of Iowa	15	50.0%	15	50.0%	30
University of Kansas	19	59.4%	13	40.6%	32
University of Kentucky	6	46.2%	7	53.8%	13

Table 3

NE Louisiana University	10	20.4%	39	79.6%	49
Xavier	20	25.6%	58	74.4%	78
University of Maryland	43	51.2%	41	48.8%	84
Massachusetts College	100	32.8%	205	67.2%	305
Northeastern University (Massachusetts)	34	39.5%	52	60.5%	86
Ferris State University (Michigan)	26	30.2%	60	69.8%	86
University of Michigan	40	47.6%	44	52.4%	84
Wayne State University	17	38.6%	27	61.4%	44
University of Minnesota	40	54.1%	34	45.9%	74
University of Mississippi	5	45.5%	6	54.5%	11
St Louis College of Pharmacy	32	40.0%	48	60.0%	80
University of Missouri (Kansas City)	11	40.7%	16	59.3%	27
University of Montana	16	57.1%	12	42.9%	28
Creighton University (Nebraska)	97	49.5%	99	50.5%	196
University of Nebraska	30	50.8%	29	49.2%	59
Rutgers College	2	100.0%	0	0.0%	2
University of New Mexico	53	34.6%	100	65.4%	153
Western	314	65.0%	169	35.0%	483
Midwestern University of Chicago	1	50.0%	1	50.0%	2
Long Island University (A&M Schwartz)	65	30.4%	149	69.6%	214
St. John's University (New York)	22	31.9%	47	68.1%	69
SUNY – Buffalo	12	54.5%	10	45.5%	22
Union U Albany College of Pharmacy	9	50.0%	9	50.0%	18

Table 3

University of North Carolina	19	54.3%	16	45.7%	35
North Dakota State University	12	50.0%	12	50.0%	24
Ohio Northern University	14	35.0%	26	65.0%	40
Ohio State University	26	50.0%	26	50.0%	52
University of Cincinnati (Ohio)	9	56.3%	7	43.8%	16
University of Toledo	18	48.6%	19	51.4%	37
Southwestern Oklahoma State University	8	57.1%	6	42.9%	14
University of Oklahoma	8	50.0%	8	50.0%	16
Oregon State University	45	47.9%	49	52.1%	94
Duquesne	23	33.8%	45	66.2%	68
Philadelphia College of Pharmacy	32	35.2%	59	64.8%	91
Temple University	31	34.4%	59	65.6%	90
University of Pittsburgh	20	55.6%	16	44.4%	36
University of Puerto Rico	3	30.0%	7	70.0%	10
University of Rhode Island	8	38.1%	13	61.9%	21
Medical University of South Carolina	1	11.1%	8	88.9%	9
University of South Carolina	7	77.8%	2	22.2%	9
South Dakota State University	1	100.0%	0	0.0%	1
University of Tennessee	6	37.5%	10	62.5%	16
University of Houston	24	36.9%	41	63.1%	65
University of Texas	14	66.7%	7	33.3%	21
Texas Southern University	4	22.2%	14	77.8%	18
Texas Tech University	2	50.0%	2	50.0%	4
University of Utah	15	46.9%	17	53.1%	32
Medical College of Virginia	10	52.6%	9	47.4%	19

Table 3

University of Washington	33	64.7%	18	35.3%	51
Washington State University	15	28.8%	37	71.2%	52
University of West Virginia	7	43.8%	9	56.3%	16
University of Wisconsin at Madison	35	62.5%	21	37.5%	56
University of Wyoming	14	56.0%	11	44.0%	25
Campbell University	4	44.4%	5	55.6%	9
Nova - Southeastern	15	48.4%	16	51.6%	31
Wilkes University	3	30.0%	7	70.0%	10
Bernard J Dunn	4	66.7%	2	33.3%	6
Midwestern Arizona	33	37.1%	56	62.9%	89
Unclassified	6	24.0%	19	76.0%	25
Other/Foreign Graduate	334	30.7%	755	69.3%	1089
Total # of Candidates (Does not include regrade results)	4,524	53.4%	3,943	46.6%	8,467

Table 4

Pass-Fail Statistics of Candidates Taking the Pharmacist Licensure Exam by Country of Pharmacist's Education 1999-2003

Graduating School Location by Country	PASS		FAIL		TOTAL
	Number	Percent	Number of Exam Attempts*	Percent	
Afghanistan	0	0.0%	4	100.0%	4
Armenia	5	31.3%	11	68.8%	16
Argentina	0	0.0%	6	100.0%	6
Australia	1	100.0%	0	0.0%	1
Austria	0	0.0%	1	100.0%	1
Azores	1	100.0%	0	0.0%	1
Bangladesh	1	20.0%	4	80.0%	5
Belgium	0	0.0%	1	100.0%	1
Bulgaria	1	11.1%	8	88.9%	9
Canada	36	76.6%	11	23.4%	47
Chile	1	16.7%	5	83.3%	6
China	6	33.3%	12	66.7%	18
Colombia	1	50.0%	1	50.0%	2
Czechoslovakia	1	33.3%	2	66.7%	3
Denmark	1	20.0%	4	80.0%	5
Egypt	24	33.3%	48	66.7%	72
Ethiopia	1	16.7%	5	83.3%	6
France	3	30.0%	7	70.0%	10
Germany	1	50.0%	1	50.0%	2
Ghana	1	50.0%	1	50.0%	2
Hungary	0	0.0%	2	100.0%	2
Israel/West Bank/Gaza Strip	1	20.0%	4	80.0%	5
India	58	33.0%	118	67.0%	176
Indonesia	1	20.0%	4	80.0%	5
Iran	13	35.1%	24	64.9%	37
Iraq	9	34.6%	17	65.4%	26
Italy	1	20.0%	4	80.0%	5
Japan	6	66.7%	3	33.3%	9
Jordan	2	28.6%	5	71.4%	7
Kenya	1	50.0%	1	50.0%	2

*Because the data has been accumulated over 10 exams, an individual who failed the exam three times would be counted in this column three times.

Korea (North & South)	18	28.1%	46	71.9%	64
Lebanon	5	33.3%	10	66.7%	15
Mexico	1	12.5%	7	87.5%	8
Nigeria/New Guinea	9	32.1%	19	67.9%	28
Pakistan	3	33.3%	6	66.7%	9
Peru	1	16.7%	5	83.3%	6
Philippines	37	15.5%	202	84.5%	239
Puerto Rico	0	0.0%	5	100.0%	5
Romania	1	50.0%	1	50.0%	2
Former USSR	8	23.5%	26	76.5%	34
Saudi Arabia	0	0.0%	2	100.0%	2
Senegal	1	50.0%	1	50.0%	2
South Africa	38	48.7%	40	51.3%	78
Spain	0	0.0%	1	100.0%	1
Sweden	1	50.0%	1	50.0%	2
Syria	2	16.7%	10	83.3%	12
Thailand	2	50.0%	2	50.0%	4
Taiwan	3	20.0%	12	80.0%	15
Turkey	0	0.0%	4	100.0%	4
Ukraine	0	0.0%	2	100.0%	2
United Kingdom	10	32.3%	21	67.7%	31
U.S.A.	4,194	56.8%	3,192	43.2%	7,386
Venezuela	0	0.0%	1	100.0%	1
Vietnam	3	18.8%	13	81.3%	16
Unknown	10	100.0%	0	0.0%	10
TOTAL	4,524	53.4%	3,943	46.6%	8,467

*Because the data has been accumulated over 10 exams, an individual who failed the exam three times would be counted in this column three times.

Supplementary Information:

1. California Business & Professions Code section 4200.1
   (as in effect until January 1, 2005)

2. California Business & Professions Code section 4200.1
   (as amended to become effective January 1, 2005)

3. California Code of Regulations Title 16, Section 1725

California Business and Professions Code Section 4200.1
In effect until January 1, 2005

4200.1. (a) Notwithstanding Section 135, commencing July 1, 1998, an applicant who fails to pass the examination required by Section 4200 after four attempts shall not be eligible for further reexamination until the applicant has successfully completed a minimum of an additional 16 semester units of education in pharmacy. The applicant shall complete a minimum of 16 semester units or the equivalent from pharmacy coursework as approved by the board. When the applicant applies for reexamination, he or she shall furnish proof satisfactory to the board that he or she has successfully completed all of the requirements of Section 4200.

(b) From July 1, 1998, to June 1, 2004, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Legislature after June 1, 2004,and before December 31, 2004, regarding the impact on those applicants of the four-attempt limit imposed by this section. The report shall include, but not be limited to, the following:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education programs.

(3) The number of applicants who, after failing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.

(4) To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

(c) This section shall remain in effect only until January 1, 2005, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2005, deletes or extends that date.

California Code of Regulations
Division 17, Title 16

§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy school approved by the American Council on Pharmaceutical Education or recognized by the board.

(b) A final examination must be a part of the course of study.

(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions
Code.

Section 4200.1 of the California Business and Professions Code

As amended by Senate Bill 1913 (Senate Business and Professions Committee, Chapter 695, Statutes of 2004)

4200.1.(a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the Multi-State Pharmacy Jurisprudence Examination for California four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.

(f) From January 1, 2004, to July 1, 2006, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2006, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

Supplementary Information:

1. California Business & Professions Code section 4200.1
   (as in effect until January 1, 2005)

2. California Business & Professions Code section 4200.1
   (as amended to become effective January 1, 2005)

3. California Code of Regulations Title 16, Section 1725